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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,221	07/18/2003	Martin O'Sullivan	50571/AW/W112	4670

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CHRISTIE, PARKER & HALE, LLP
PO BOX 7068
PASADENA, CA 91109-7068

EXAMINER	
ROANE, AARON F	
ART UNIT	**PAPER NUMBER**
3739	

DATE MAILED: 03/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/622,221	O'SULLIVAN ET AL.	
	Examiner	Art Unit	
	Aaron Roane	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 December 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,9-19 and 22-34* is/are pending in the application.

4a) Of the above claim(s) *33 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,9-19 and 22-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-29 are rejected under 35 U.S.C. 102(b) as being anticipated by Whayne et al. (USPN 6,203,525 B1).

Regarding claims 1, 2 and 17, Whayne et al. disclose a catheter for ablating tissue, the catheter comprising: an elongated generally-tubular catheter body (12 in figure 1 and its analogous counterparts in other embodiments) having proximal and distal ends; and an electrode assembly (360 in figure 36-38) at the distal end of the catheter body, the electrode assembly including a generally-straight porous electrode arrangement that is generally transverse to the catheter body, the porous electrode arrangement comprising: a non-conductive tubing (distal tubing 28 in figure 3A and its analogous counterpart in the embodiment illustrated in figure 36) mounted on-the distal end of the catheter, a mid-section of the non-conductive tubing forming a curve that first bends away from and then back toward and past the axis of the catheter body forming a generally straight distal end

of the non-conductive tubing, wherein the generally straight distal end of the non-conductive tubing forms an angle with the axis of the catheter body ranging from about 75° to about 110° (see figure 4A); one or more electrodes (the left and center electrodes 372 in figures 37 and 38) electrically connected to a suitable energy source (not shown see col. 5, lines 50-67, also see 380 in col. 22, lines 1-3), wherein the electrode(s) is mounted on the non-conductive tubing; a porous sleeve (364) mounted in surrounding relation to the one or more electrodes; and one or more irrigation openings (374) fluidly connecting the open space to a lumen (lumen of 370) extending through the catheter through which fluid can pass; wherein, in use, fluid passes through the lumen in the catheter, through the one or more irrigation openings, into the open space and through the porous sleeve, see col. 5, 6 and 21-23 and figures 1 and 36-38. Regarding the electrode assembly further comprising a non-conductive tubing mounted on the distal end of the catheter over which the one or more electrodes are mounted, and wherein the non-conductive tubing includes at least one lumen fluidly connected to the lumen in the catheter body and to the one or more irrigation openings, Whayne et al. are silent as to the tubing (370) over which the one or more electrodes are mounted is non-conductive. However, Whayne et al. certainly imply that the tubing (370) is electrically non-conductive since it discusses the use of the electrodes (372) in a bipolar mode, see col. 21. The tubing (370) would have to be non-conductive the electrodes (372) are used in bipolar mode, otherwise the tubing (372) would provide an electrical "short" between the electrodes.

Regarding claims 3 and 18, Whayne et al. further disclose the one or more electrodes comprises a single coiled electrode (22) wrapped around a portion of the non-conductive tubing, see col. 5-8 and 23.

Regarding claims 4 and 19, Whayne et al. further disclose the porous sleeve has proximal and distal ends that are bonded to the non-conductive tubing, see figure 38.

Regarding claim 6, Whayne et al. further disclose the generally straight porous electrode forms an angle with the axis of the catheter body ranging from about 75° to about 110°, see col. 5-23 and figures 1-39.

Regarding claims 9, 10, 22 and 23, Whayne et al. further the porous sleeve comprises a polytetrafluoroethylene (PTFE) that is expandable to no more than 10% at a distilled water flow rate of 30 to 40 cc/min, see col. 21 and 22.

Regarding claims 11 and 24, Whayne et al. further disclose the porous sleeve comprises a material selected from the group consisting of porous nylon, sintered ceramics, woven meshes and cellular foam, see col. 22, line 39-57.

Regarding claims 12, 13, 25 and 26, Whayne et al. disclose the claimed invention, see col. 5-25 and particularly col. 23.

Regarding claims 14 and 27, Whayne et al. further disclose the electrode assembly further comprises one or more ring electrodes (the right electrode 372 in figures 37 and 38) mounted proximal and/or distal to the porous electrode (the left and center electrodes 372 in figures 37 and 38).

Regarding claims 15, 16, 28 and 29, Whayne et al. further disclose the electrode assembly further comprises one or more temperature sensors (see for example 292 figure 29), wherein the one or more temperature sensors are mounted under the porous sleeve, see col. 23-25 and figure 29.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (USPN 6,203,525 B1) in view of Fung et al. (USPN 6,120,476).

Regarding claims 30 and 31, Whayne et al. disclose the claimed invention except that a pre-shaped support wire made of nitinol extends through a second lumen of the non-conductive tubing. Whayne et al. clearly discloses a first lumen (lumen of 370) used for irrigation, see col. 5, 6 and 21-23 and figures 1 and 36-38. Whayne et al. also disclose the use of a nitinol pre-shaped support wire (26) located in a lumen of a non-conductive tubing (28 and/or 28'). However, Whayne et al. do not disclose simultaneously disposing a nitinol pre-shaped support wire in one lumen of the non-conductive tubing and the having an irrigating pathway/passage in other separate lumen. Fung et al. disclose an irrigated tip-catheter that has at least two lumens and teach the provision of the non-conductive tubing (19) upon which electrodes (38) are placed with three lumens 30, 32 and 34, see col. 4-6 and figure 3. Additionally, Fung et al. teach the simultaneous provision of a pre-shaped nitinol wire (42) placed in one lumen (32) in order to provide steerability/deflection of the device and the use of another lumen (34) as an irrigation lumen in order to provide infusion, see col. 4-6 and figure 3. Therefore, at the time of the invention it would have been obvious to modify the invention of Whayne et al., as taught by Fung et al., to simultaneously provide the pre-shaped nitinol wire placed in one lumen in order to provide steerability/deflection of the device and the use of another lumen as an irrigation lumen in order to provide infusion.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Whayne et al. (USPN 6,203,525 B1) in view of Swanson et al. (USPN 5,961,513).

Regarding claim 32, Whayne et al. disclose the claimed invention except for reciting the one or more irrigation openings are located only on the side of the porous electrode that is to be in contact with tissue to be ablated. It is well known in the art to place or provide holes/pores of a porous material in a particular pattern and/or on a side of the otherwise porous material in order to achieve a particular ablation pattern. Swanson et al. disclose a tissue heating and/or ablating device and teach providing the expandable porous element (22) with holes/pores located on one side in order to achieve a particular ablation pattern and/or serve as a sensing surface, see col. 5-21 and figures 1-14. Therefore at the time of the invention it would have been obvious to one of ordinary skill in the art to modify the invention of Whayne et al., as is well known in the art and taught by Swanson et al., to provide the expandable porous element with holes/pores located on one side in order to achieve a particular ablation pattern and/or serve as a sensing surface.

Response to Arguments

Applicant's arguments filed 12/29/2005 have been fully considered but they are not persuasive. On page 8, 2nd paragraph of the noted response, Applicant asserts that Whayne et al. neither teach nor suggest "a non-conductive tubing mounted on the distal end of the catheter, a mid-section of the non-conductive tubing forming a curve that first bends away from and then back toward and past the axis of the catheter body forming a generally straight distal end of the non-conductive tubing," see lines 3-6. However, the examiner strongly disagrees and has

highlighted column and line of the Whayne et al. patent which discloses the above claimed non-conductive tubing having the various claimed features. Applicant then goes on to assert that Whayne et al. disclose a "loop structure." Although it is Applicant's right to a particular interpretation to which the examiner neither agrees or disagrees, the claim language (particularly of claims 1 and 17) does not distinguish over the Whayne et al. patent. It should be pointed out, that although operational characteristics of an apparatus may be apparent from the specification, we will not read such characteristics into the claims when they cannot be fairly connected to the structure recited in the claims. See In re Self, 671 F.2d 1344, 1348, 213 USPQ 1, 5 (CCPA 1982).

This action is FINAL.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aaron Roane whose telephone number is (571) 272-4771. The examiner can normally be reached on Monday-Thursday 7AM-6PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A.R. A.R.
March 10, 2006

MICHAEL PEFFLEY
PRIMARY EXAMINER